

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of )  
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Malcolm KING et al ) Prior Group Art Unit: 1623  
 )  
Application No.: Continuation of U.S. Patent ) Prior Examiner: Devish Khare  
Appln. No. 09/052,614, filed March 31, 1998 )  
 )  
Filed: June 28, 2001 )  
 )  
For: USE OF DEXTRAN AND OTHER )  
POLYSACCHARIDES TO IMPROVE )  
MUCUS CLEARANCE )

**PRELIMINARY AMENDMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Prior to the examination of the above-identified patent application, please enter the following amendments.

**IN THE SPECIFICATION**

Kindly insert the following paragraph on page 1, before line 5:

--This application is a continuation of U.S. Patent Application No. 09/052,614, filed March 31, 1998.--

**IN THE CLAIMS**

Please delete original claims 1-12 without prejudice or disclaimer.

Please add new claims 13-37 as follows:

--13. A method of improving mucus clearance comprising administering to the respiratory tract of a patient in need of such treatment an effective amount of a polysaccharide having about the same number of hydrogen bonding sites as dextran.

14. A method of improving mucus clearance comprising administering to the respiratory tract of a patient in need of such treatment an effective amount of a polysaccharide having sugar moieties that stereochemically complement the oligosaccharide moieties native to the respiratory tract mucins in the manufacture of a medicament to improve mucus clearance.

15. The method of claim 14, wherein the polysaccharide comprises oligomers of galactose and fucose and the amino sugars glucosamine and galactosamine.

16. The method of claim 13, wherein the polysaccharide is administered in admixture with a pharmaceutically acceptable diluent or carrier.

17. The method of claim 16, wherein the diluent is sodium chloride or ringer solution.

18. The method of claim 13, wherein the polysaccharide is administered to the respiratory tract topically or by aerosol.

19. The method of claim 13, wherein the polysaccharide is present in the respiratory secretion at a concentration of about 4 mg/ml to about 40 mg/ml.

20. The method of claim 14, wherein the polysaccharide is administered in admixture with a pharmaceutically acceptable diluent or carrier.

21. The method of claim 20, wherein the diluent is sodium chloride or ringer solution.

22. The method of claim 14, wherein the polysaccharide is administered to the respiratory tract topically or by aerosol.

23. The method of claim 14, wherein the polysaccharide is present in the respiratory secretion at a concentration of about 4 mg/ml to about 40 mg/ml.

24. A method of treating lung disease associated with impaired mucus clearance comprising administering to the respiratory tract of a patient in need of such treatment an effective amount of a polysaccharide having about the same number of hydrogen bonding sites as dextran.

25. The method of claim 24, wherein the lung disease is cystic fibrosis, chronic bronchitis, bronchiectasis or bronchial asthma.

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31. The method of claim 29, further comprising the step of assessing viscosity and elasticity of sputum of said patient following the treatment.

32. The method according to claim 29, wherein the polysaccharide is present in the respiratory secretion at a concentration of about 4 mg/ml to about 40 mg/ml.

33. A method of improving mucus clearability in a patient having cystic fibrosis comprising administering to the respiratory tract of a patient in need of such treatment an effective amount of a polysaccharide having sugar moieties that stereochemically complement the oligosaccharide moieties native to the respiratory tract mucins in the manufacture of a medicament to improve mucus clearance.

34. The method of claim 33, wherein the polysaccharide comprises oligomers of galactose and fucose and the amino sugars glucosamine and galactosamine.

35. The method of claim 33, further comprising the step of assessing liquification of secretions of said patient following treatment.

36. The method of claim 33, further comprising the step of assessing viscosity and elasticity of sputum of said patient following the treatment.

37. The method according to claim 33, wherein the polysaccharide is present in the respiratory secretion at a concentration of about 4 mg/ml to about 40 mg/ml.--

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**REMARKS**

Prior to examination, entry of the foregoing is respectfully requested.

Original claims 1-12 have been deleted in favor of new claims 13-37 presented herein. Support for these claims may be found at the very least in the specification as originally filed at page 4, ln. 21 - page 4, ln. 10; page 8, lines 5-20; and in the original claims.

The specification has also been amended to indicate the parent application from which priority is claimed.

In the event that there are any questions relating to this Preliminary Amendment, or to the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney at (508) 339-3684 concerning such questions so that prosecution of this application may be expedited.

Early and favorable action in the form of a Notice of Allowance is respectfully requested and believed to be in order.

Respectfully submitted,

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